

400 Seventh St., S.W. Washington, D.C. 20590

JUL 1 3 2001

Ms. Carol McCulley Explant Services World Heart, Inc. 7799 Pardee Lane Oakland, CA 94612

Reference No.: 01-0120

This is in response to your May 10, 2000 letter requesting clarification of the proper shipping name for a Formaldehyde solution containing 10% neutral buffered formalin under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask whether the proper shipping name should be "Environmentally hazardous substances, liquid, n.o.s." or "Aviation regulated liquid, n.o.s."

Either shipping name may be used, however, the preferred proper shipping name is "Aviation regulated liquid, n.o.s." The entry "Aviation regulated liquid, n.o.s." was added to the § 172.101 Hazardous Materials Table in a final rule published March 5, 1999 (Docket HM-215C; 64 FR 10741) for alignment with the ICAO Technical Instructions and the UN Recommendations.

I trust you find the information helpful.

Holle L. Mitall

Hattie L.Mitchell

Chief, Regulatory Review and Reinvention

Office of Hazardous Materials Standards

01-0120

172.101

WORLDHEORT

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www.worldheart.com



10 May, 2000

Attention: Edward Mazzulo
Director of Hazardous Materials Standards
Department of Transportation
400 7th Street, SW
Washington, D.C. 20590

Dear Mr. Mazzulo:

We provide a shipping box for our customers to return our Left Ventricular Assist Device when it is removed from a patient. The box contains a total amount of approximately 560 ml of 10% neutral buffered formalin in five containers when returned to us. We do not provide the 10% neutral buffered formalin.

Currently, our shipping information is: Environmentally hazardous substances, liquid, n.o.s. (formaldehyde), UN3082, packing group III, hazard class 9. I have MSDS forms from various manufacturers of 10% neutral buffered formalin. They disagree as to the proper shipping name and UN classification. I have been informed by the manufacturer of the shipping box we use that the correct information should now be: Aviation regulated liquid, n.o.s. (10% buffered formalin), UN3334, no packing group, hazard class 9.

We would appreciate confirmation that Aviation regulated liquid, n.o.s. (10% buffered formalin) UN3334, no packing group, hazard class 9 is the proper shipping name/description and shipping information.

Thank you very much.

Regards,

Carol McCulley Explant Services World Heart, Inc.

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carol.mcculley@worldheart.com (e-mail)

Attachments: 4 MSDS forms from various manufacturers